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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,384	12/23/2003	Richard Eric Rothman	001107.000412	7753

22907 7590 08/07/2006

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WASHINGTON, DC 20001

EXAMINER
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WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/743,384

Applicant(s)

ROTHMAN ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/05; 8/05; 12/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

#### **DETAILED ACTION**

1. Applicant's preliminary amendment filed on 12/23/2003 is acknowledged. Claims 1 and 16 have been amended. Claims 43-52 have been canceled. Claims 1-42 are pending.

#### ***Status Identifier***

2. The amendment filed on 12/23/2003 is considered non-compliant because it fails to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see 68 *Fed. Reg.* 38611, June 30 2003). The following caused the amendment document to further be non-compliant: Each claim has not been provided with the proper status identifier. Specifically, claims 1 and 16 are identified as "Original" which is not a proper identifier. The claims should be identified at "Currently Amended" because the claims do not recited the limitations as originally filed.

For further explanation of the amendment format required by 37 CFR 1.121, See MPEP, see 714 and the USPTO website at:  
<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer/pdf>.

#### ***Sequence Listing***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth: The claims 4-6 and 19-21 contain a reference to a nucleotide sequences of ten or more nucleotides not represented by a sequence identifier (SEQ ID NO:). Appropriate correction is necessary.

***Specification***

4. The disclosure is objected to because of the following informalities:

The use of the trademark "TAQMAN", "AMPLITAQ" and "MICROCON YM-100" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112: New Matter***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "*Rhizobium Japonicum*" is not supported by the specification as originally found. The specification teaches that the second divergent region is found in *Bradyrhizobium Japonicum* 16S rRNA gene. The specification provides three Genbank accession numbers at page 8 for the 16S rRNA gene sequence of "*Bradyrhizobium*

Art Unit: 1637

*Japonicum*". The specification provides no teaching anywhere for 16S rRNA gene from *Rhizobium Japonicum*. Further the prior art teaches that *Bradyrhizobium Japonicum* and *Rhizobium Japonicum* are significantly different strains (see Masterson et al, Journal of Bacteriology, vol. 163, no. 1, pages 21-26, 1985). Therefore, the specification would not have suggested to the skilled artisan that the Applicant was in possession of the claimed invention as of filing date.

***Claim Rejections - 35 USC § 112 second paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-42 are confusing in claims 1 and 16 for the limitation:

"wherein the primers amplify a segment of a *S. aureus* 16S rRNA gene comprising a conserved region and a first divergent region, wherein the conserved region comprises at least 18 contiguous nucleotides which are at least 80% identical among at least 10 eubacterial species wherein the first divergent region comprises at least 10 contiguous nucleotides and differs by at least 3 nucleotides from a second divergent region found in *Rhizobium japonicum* 16S rRNA gene",

because it is unclear as to what "segment" of the *S. aureus* 16S rRNA gene the primers is actually amplifying. It appears that Applicant has described properties of the *S. aureus* 16S rRNA gene, but the nexus between these properties as it relates to the divergent region of *Rhizobium Japonicum* and the step of amplifying a segment of *S. aureus* 16S rRNA gene with primers is unclear. It appears that the primer can amplify

any segment of the *S. aureus* 16S RNA gene. How this relates to determining a first species of eubacterial in a sample is ambiguous and unclear. Clarification is required.

***Closest Prior art***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reischl et al (Journal of Clinical Microbiology, vol. 38, no. 6, page 2429-2433, June 2000) teach a method of identification of methicillin-resistant *S. aureus* and simultaneous species confirmation using real-time fluorescence PCR.

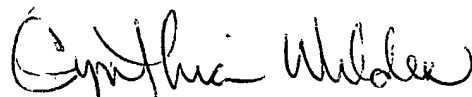
***Conclusion***

10. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.  
Patent Examiner  
Art Unit 1637

7/31/2006